FORM PTO-1083

Docket No.: 300.1023
Date: April 10, 2006

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

In re application of: Chih-Ming Chen, et al.
Serial No.: 09/726,193
Filed: November 29, 2000
For: **CONTROLLED RELEASE METFORMIN FORMULATIONS**

S i r:

Transmitted herewith is a **Supplemental Information Disclosure Statement** in the above-identified application.

[ ] Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
[ ] Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
[X] No fee for additional claims is required.
[ ] A filing fee for additional claims calculated as shown below, is required:

[X] Also transmitted herewith are:
[ ] Petition for extension under 37 C.F.R. 1.136
[X] Other:- **Form PTO-1449 (2 sheets) and copies of references cited therein**

[X] Check(s) in the amount of **$180.00** is/are attached to cover:
[ ] Filing fee for additional claims under 37 C.F.R. 1.16
[ ] Petition fee for extension under 37 C.F.R. 1.136
[X] Other: **Information Disclosure Statement Fee**

[X] The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
[ ] Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
[X] Any patent application processing fees under 37 C.F.R. 1.17.
[X] Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

Robert J. Paradiso, Reg. No. 41,240
DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
Tel: (212) 736-1940
Fax: (212) 736-2427

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450". on April 10, 2006 .
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	09/726,193
Applicant:	Chih-Ming CHEN, et al.
Filed:	November 29, 2000
TC/A.U.	1615
Examiner:	B. Fubara
For:	**CONTROLLED RELEASE METFORMIN FORMULATIONS**
Docket No.:	300.1023
Customer No.:	23280

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

April 10, 2006

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (2 sheets) for consideration by the Examiner in connection with the examination of the above-identified patent application.

In accordance with 37 C.F.R. § 1.98 (a)(2), copies of the references listed in the FOREIGN PATENT DOCUMENTS and OTHER PRIOR ART REFERENCES sections of the accompanying Form PTO-1449 are enclosed. If it is determined that a copy of any of the listed references is not presently enclosed, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

Additionally, Applicants direct the Examiner's attention to reference "BQ" on the enclosed Form PTO-1449. Reference "BQ" is data from a biostudy which was performed using

formulations prepared in accordance with the present application. It is noted that the exemplified formulations did not provide a T_{max} between 8-12 hours, except when the formulation prepared in accordance with Example 3 was administered at dinner. As set forth in the accompanying biostudy data, the mean T_{max} values for the Examples of the present application were as follows: Example 1 (fasting) 4.67 hours (*See, e.g.*, pages 1 and 3 of the biostudy); Example 2 (fasting) 4.33 hours (*See, e.g.*, pages 10 and 12 of the biostudy); Example 2 (fed a.m.) 6.80 hours (*See, e.g.*, pages 13, 14 and 16 of the biostudy); Example 3 (fed a.m.) 6.67 hours (*See, e.g.*, pages 4 and 6 the biostudy); Example 3 (Fed p.m.) 9.67 hours (*See, e.g.*, pages 17 and 20 of the biostudy). Therefore, the only instance that the T_{max} was between 8-12 hours was Example 3 fed in the P.M. (at dinner).

In addition, pages 2, 5, 11, 15, 19 of the biostudy data includes plasma concentration v. time graphs and data for formulations prepared in accordance with Examples 1(fasting), 3 (fed), 2 (fasting), 2 (fed), and 3 (fed), respectively, of the present application; pages 8 and 9 of the biostudy data include plasma concentration v. time graphs and data for formulations prepared in accordance with Example 2 (fasting and fed) and Example 3 (fed a.m. and p.m.) of the present application; and pages 7 and 18 include plasma concentration v. time graphs and data for formulations prepared in accordance with Example 3 (fed a.m. and p.m.) of the present application.

Applicants also respectfully advise the Examiner of the following co-pending U.S. patent applications which are commonly assigned to the owners of the instant application:

U.S. Patent Application Serial No. 11/117,999, "Controlled Release Metformin Compositions," filed April 29, 2005, published on February 16, 2006 as U.S. Publication No. 2006/0034922, listed as reference "BI" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/796,411, "Controlled Release Metformin Compositions," filed March 9, 2004, published on November 4, 2004 as U.S. Publication No. 2004/0219209, listed as reference "BH" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/225,741, "Controlled Release Metformin Compositions," filed September 13, 2005, published on January 12, 2006 as U.S. Publication No. 2006/0008525, listed as reference "BJ" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/224,784, "Controlled Release Metformin Compositons," filed September 13, 2005, published on January 12, 2006 as U.S. Publication No. 2006/0008523, listed as reference "BL" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/224,785, "Controlled Release Metformin Compositions," filed September 13, 2005, published on January 12, 2006 as U.S. Publication No. 2006/0008524, listed as reference "BK" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/225,742, "Controlled Release Metformin Compositions," filed September 13, 2005, published on January 12, 2006 as U.S. Publication No. 2006/0008526, listed as reference "BM" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/442,692, "Biguanide formulations," filed May 20, 2003, published on March 18, 2004 as U.S. Publication No. 2004/0052848, listed as reference "BN" on the enclosed Form PTO-1449.

It is respectfully requested that the reference cited in the accompanying Form PTO-1449 (2 sheets) be considered and made of record.

This Information Disclosure Statement is being filed after a First Office Action but before a Final Office Action or Notice of Allowance. Pursuant to 37 C.F.R. § 1.98(c), a check for $180.00 is enclosed to cover the required fee. However, if it is determined that any additional fee is due or an overpayment has been made, the Examiner is authorized to charge said fee or credit said overpayment to our Attorney Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940

FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 300.1023	SERIAL NO.: 09/726,193
	LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT(S): CHEN et al.	
		FILING DATE: November 29, 2000	GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AB							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AC	Approval letter from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 000, October 13, 2000
	AD	Approved Label for Glucophage/Glucophage XR, NDA 21-202, Supplement 000, October 13, 2000
	AE	Approval letter on labeling revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 003, January 8, 2002
	AF	Approval letter on formulation revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 008, April 11, 2003
	AG	Approval letter on labeling revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 011, March 19, 2004
	AH	Approval letter on labeling revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 013, March 19, 2004
	AI	Approval letter on labeling revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 001, April 19, 2001
	AJ	Approved Label For Glucophage/Glucophage XR NDA 21-202, Supplement 013, March 19, 2004
	AK	Approved Label for Glucophage/Glucophage XR NDA 21-202, Supplement 011, March 19, 2004
	AL	Approved Label for Glucophage/Glucophage XR NDA 21-201, Supplement 008, labeling revision, April 11, 2003
	AM	
	AN	
	AO	
	AP	
	AQ	
	AR	
	AS	

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 300.1023	SERIAL NO.: 09/726,193
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		FILING DATE: November 29, 2000	GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA	6 1 1 7 4 5 1	09/12/00	Kumar	424	465	
	BB	6 8 6 6 8 6 6	03/15/05	Chen et al.	424	468	
	BC	6 7 9 0 4 5 9	09/14/04	Cheng et al.	424	468	
	BD	5 9 2 2 7 6 9	07/13/99	Barelli et al.	514	616	
	BE	6 0 5 1 5 9 7	04/18/00	Zhang et al.	514	414	
	BF	6 0 1 1 0 4 9	01/04/00	Whitcomb	514	369	
	BG	6 1 6 1 1 6 2	02/20/01	Byrd et al.	514	440	
	BH	20 04 02 19 2 0 9	11/04/04	Chen et al.			
	BI	20 06 00 34 9 2 2	02/16/06	Cheng et al.			
	BJ	20 06 00 08 5 2 5	01/12/06	Chen et al.			
	BK	20 06 00 08 5 2 4	01/12/06	Chen et al.			
	BL	20 06 00 08 5 2 3	01/12/06	Chen et al.			
	BM	20 06 00 08 5 2 6	01/12/06	Chen et al.			
	BN	20 04 00 52 8 4 8	03/18/04	Cheng et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	BO	2 2 5 1 4 3 0	02/28/00	CA	A61K	31/44		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	BP	E.K. Kastrup: "Anidiabetic Agents," DRUG FACTS AND COMPARISONS, 1999, St. Louis, pp 635-642
	BQ	Andrx Pilot Biostudy Data (20 pages)
	BR	Chiao, C. Sustained-Release Drug Delivery Systems; Remington: the Science and Practice of Pharmacy, 1995, Mack Publishing Company, Easton PA pgs. 1660-1669
	BS	Drug Facts and Comparisons pages 130n-130u (1999)

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.